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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,750	01/16/2001	Ichiro Azuma	0020-4802P	7730

2292 7590 04/11/2006

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/743,750	AZUMA ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-8, 10--11 and 13-26* is/are pending in the application.

4a) Of the above claim(s) *1-3,5-8 and 13-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 January 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *11/29/05*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

1. This Office Action is responsive to Applicant's amendment and response filed July 13, 2004. Claim 21 has been amended.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

Interview

3. An interview was held with Mr. Nuell on November 29, 2005. In this interview Applicant explained the essence of the invention. Applicant asserted that the invention was patentable over the prior art of record. Declarations submitted by Dr. Kawabe and Dr. Nomura were discussed. Applicant provided new photocopies of the photographs were included in the declarations for clarity purposes. The Examiners informed Mr. Nuell that the comments made in the interview as well as the response would be considered. No determination of patentability was made in the interview. See attached interview summary.

Rejections Maintained

4. The rejection under 35 U.S.C. 102(b) is maintained for claims 21, 23-25 and 26 for the reasons set forth on pages 3-5 paragraph 3 of the previous Office Action.

The rejection was on the grounds that Yamamura et al teach compositions comprising *Nocardia ruba* cell wall skeleton, squalene, a suspending agent and dispersing agent (see the Abstract). Yamamura et al teach that cell wall skeleton used in the invention can be derived from *Mycobacterium bovis* (column 2, lines 15-21). Yamamura et al teach the composition was prepared using suspending agents such as Tween and Span (surfactants) (column 2, lines 54-68). Claim limitations such as "wherein the emulsion is negative for agglutination reaction with lectin", "having an particle diameter of about 100 μm or less is homogeneously dispersed" and "wherein the particle diameter is about 25 μm" would be inherent in the teachings of the prior art. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil (squalane). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 29222-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Yamamura et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that the claims are written in product-by-process terms. Applicant urges that the prior art does not teach or suggest that an organic solvent should be used during the preparation of an emulsion of the BCG-CWS. Applicant refers to the two Declarations filed under 37 CFR 1.132 of Dr. Nomura I and II and Dr. Kawabe. Applicant urges that the declarations are submitted to demonstrate the difference in particle size of the BCG-CWS composition using a solvent to prepare the BCG-CWS compositions and preparing the CWS without the use of a solvent. Applicant urges that the Nomura II declaration shows that the including a solvent in the step of dispersing the BCG-CWS in the oil provides an emulsion having a more uniform particle size that lacks any large aggregates.

Applicant's arguments filed February 2, 2006 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is urging process limitations in a product claim. The claims are directed to an oil-in-water emulsion (a product) which comprises a Bacillus Calmette-Guerin cell wall skeleton encapsulated in an oil. It should be remembered that MPEP 2113 states:

> [E]ven though product-by-pro-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from the a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

Yamamura et al teach compositions comprising *Nocardia ruba* cell wall skeleton, squalene, a suspending agent and dispersing agent. Yamamura et al teach that cell wall skeleton used in the invention can be derived from *Mycobacterium bovis*.

Claim limitations such as particle diameter of droplets would be inherent in the teachings of the prior art. Thus, the prior art anticipates the claimed invention.

To address Applicant's comments regarding the Declaration I of Dr. Nomura, it appears the declaration is submitted to argue the difference in particle size of the BCG-CWS composition. The declaration compares using solvents and not using solvents to prepare the BCG-CWS composition. However, the declaration does not compare the oil-in-water of the prior art with the instantly claimed oil-in-water emulsion. There is no evidence provided to show that the claimed emulsion differs from that of the prior art since no comparison has been provided.

To address Applicant's comments regarding the Declaration of Dr. Kawabe which is submitted to show the differences between the morphologies of BCG-CWS suspended in a solvent (e.g. toluene) and the morphologies of BCG-CWS suspended in saline, it appears the data in this declaration is not relevant to the claimed invention which is directed to a oil-in-water emulsion and not a method of preparing an emulsion.

Although the use of a solvent such as ethanol or toluene is used in the process of making the claimed emulsion as evidenced by the Declaration II of Dr. Nomura, it should be noted that the prior art teaches that ethanol and acetone were both used in the preparation of the cell wall components of the oil-in-water emulsion (column 9).

There is nothing on the record to show that the oil-in-water emulsion of the prior art is not the same as the claimed oil-in-water emulsion.

5. The rejection under 35 U.S.C. 102(b) is maintained for claims 21, 23-25 and 26 for the reasons set forth on pages 6-7 paragraph 8 of the previous Office Action.

The rejection was on the grounds that Cantrell teaches vaccines comprising cell wall skeleton which is obtained from microorganisms including *Nocardia rubra* and *Mycobacterium bovis* (column 4, lines 54-68) and squalene (oil). Cantrell teaches that the oil is combined with a detergent (i.e. Tween or Arlacel) (surfactant) (column 7, lines 27-35). Cantrell teaches the formation of oil droplet emulsions (column 7, lines 35-40 and column 10). Claim limitations such as "wherein the emulsion is negative for agglutination reaction with lectin", "having an particle diameter of about 100 μm or less is homogeneously dispersed" and "wherein the particle diameter is about 25 μm" would be inherent in the teachings of the prior art. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil (squalane). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Cantrell anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that the claims are written in product-by-process terms. Applicant urges that the prior art does not teach or suggest that an organic solvent should be used during the preparation of an emulsion of the BCG-CWS. Applicant refers to the two Declarations filed under 37 CFR 1.132 of Dr. Nomura I and II and Dr.

Kawabe. Applicant urges that the declarations are submitted to demonstrate the difference in particle size of the BCG-CWS composition using a solvent to prepare the BCG-CWS compositions and preparing the CWS without the use of a solvent. Applicant urges that the Nomura II declaration shows that the including a solvent in the step of dispersing the BCG-CWS in the oil provides an emulsion having a more uniform particle size that lacks any large aggregates.

Applicant's arguments filed February 2, 2006 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is urging process limitations in a product claim. The claims are directed to an oil-in-water emulsion (a product) which comprises a Bacillus Calmette-Guerin cell wall skeleton encapsulated in an oil. It should be remembered that MPEP 2113 states:

> [E]ven though product-by-pro-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from the a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

Cantrell teaches vaccines comprising cell wall skeleton which is obtained from microorganisms including *Nocardia rubra* and *Mycobacterium bovis* and squalene (oil). Cantrell teaches that the oil is combined with a detergent (i.e. Tween or Arlacel) (surfactant). Cantrell teaches the formation of oil droplet emulsions. Claim limitations such as particle diameter of droplets would be inherent in the teachings of the prior art. Thus, the prior art anticipates the claimed invention.

To address Applicant's comments regarding the Declaration of Dr. Nomura, it appears the declaration is submitted to argue the difference in particle size of the BCG-

CWS composition. The declaration compares using solvents and not using solvents to prepare the BCG-CWS composition. However, the declaration does not compare the oil-in-water of the prior art with the instantly claimed oil-in-water emulsion. There is no evidence provided to show that the claimed emulsion differs from that of the prior art since no comparison has been provided.

To address Applicant's comments regarding the Declaration of Dr. Kawabe which is submitted to show the differences between the morphologies of BCG-CWS suspended in a solvent (e.g. toluene) and the morphologies of BCG-CWS suspended in saline, it appears the data in this declaration is not relevant to the claimed invention which is directed to a oil-in-water emulsion and not a method of preparing an emulsion.

Although the use of a solvent such as ethanol or toluene is used in the process of making the claimed emulsion as evidenced by the Declaration II of Dr. Nomura, it should be noted that the prior art teaches that ethanol and acetone were both used in the preparation of the cell wall components of the oil-in-water emulsion (column 9).

There is nothing on the record to show that the oil-in-water emulsion of the prior art is not the same as the claimed oil-in-water emulsion.

6. The rejection under 35 U.S.C. 102(b) is maintained for claims 21, 23-25 and 26 for the reasons set forth on pages 6-7 paragraph 8 of the previous Office Action.

The rejection was on the grounds that Yarkoni et al teach oil-in-water emulsions comprising *Mycobacterium bovis* BCG cell walls, squalane and Tween (surfactant) (page 881). Claim limitations such as "wherein the emulsion is negative for agglutination reaction with lectin", "having an particle diameter of about 100 μm or less is homogeneously dispersed" and "wherein the particle diameter is about 25 μm" would be inherent in the teachings of the prior art. The products of the prior art reference

appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil (squalane). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Yarkoni et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that the claims are written in product-by-process terms. Applicant urges that the prior art does not teach or suggest that an organic solvent should be used during the preparation of an emulsion of the BCG-CWS. Applicant refers to the two Declarations filed under 37 CFR 1.132 of Dr. Nomura I and II and Dr. Kawabe. Applicant urges that the declarations are submitted to demonstrate the difference in particle size of the BCG-CWS composition using a solvent to prepare the BCG-CWS compositions and preparing the CWS without the use of a solvent. Applicant urges that the Nomura II declaration shows that the including a solvent in the step of dispersing the BCG-CWS in the oil provides an emulsion having a more uniform particle size that lacks any large aggregates.

Applicant's arguments filed February 2, 2006 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is urging process limitations in a product claim. The claims are directed to an oil-in-water emulsion (a product) which comprises a Bacillus Calmette-Guerin cell wall skeleton encapsulated in an oil. It should be remembered that MPEP 2113 states:

> [E]ven though product-by-pro-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from the a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

Yarkoni et al teach oil-in-water emulsions comprising *Mycobacterium bovis* BCG cell walls, squalane and Tween (surfactant) (page 881). Claim limitations such as particle diameter of droplets would be inherent in the teachings of the prior art. Thus, the prior art anticipates the claimed invention.

To address Applicant's comments regarding the Declaration of Dr. Nomura, it appears the declaration is submitted to argue the difference in particle size of the BCG-CWS composition. The declaration compares using solvents and not using solvents to prepare the BCG-CWS composition. However, the declaration does not compare the oil-in-water of the prior art with the instantly claimed oil-in-water emulsion. There is no evidence provided to show that the claimed emulsion differs from that of the prior art since no comparison has been provided.

To address Applicant's comments regarding the Declaration of Dr. Kawabe which is submitted to show the differences between the morphologies of BCG-CWS suspended in a solvent (e.g. toluene) and the morphologies of BCG-CWS suspended in

saline, it appears the data in this declaration is not relevant to the claimed invention which is directed to a oil-in-water emulsion and not a method of preparing an emulsion.

Although the use of a solvent such as ethanol or toluene is used in the process of making the claimed emulsion as evidenced by the Declaration II of Dr. Nomura, it should be noted that the prior art teaches that ethanol and acetone were both used in the preparation of the cell wall components of the oil-in-water emulsion (column 9).

There is nothing on the record to show that the oil-in-water emulsion of the prior art is not the same as the claimed oil-in-water emulsion.

7. The rejection under 35 U.S.C. 102(b) is maintained for claims 21, 23-25 and 26 for the reasons set forth on pages 4-6 paragraph 7 of the previous Office Action.

The rejection was on the grounds that Van Nest et al teach compositions (oil-in-water emulsions) comprising bacterial components, oils, emulsifying agents (dispersion-aiding solvent), detergents (surfactants) in the form of oil droplets (see the Abstract). Van Nest et al teach that the composition of the invention comprise cell wall skeleton from *Mycobacteria* (column 9, lines 8-15). Van Nest et al teach that the oils used in the composition include squalene (column 4, lines 45-48). Van Nest et al teach that emulsifying agents include in the composition include ethanol (column 10, lines 58-63). Claim limitations such as "wherein the emulsion is negative for agglutination reaction with lectin", "having an particle diameter of about 100 μm or less is homogeneously dispersed" and "wherein the particle diameter is about 25 μm" would be inherent in the teachings of the prior art. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil (squalane). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or

practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Van Nest et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that the claims are written in product-by-process terms. Applicant urges that the prior art does not teach or suggest that an organic solvent should be used during the preparation of an emulsion of the BCG-CWS. Applicant refers to the two Declarations filed under 37 CFR 1.132 of Dr. Nomura I and II and Dr. Kawabe. Applicant urges that the declarations are submitted to demonstrate the difference in particle size of the BCG-CWS composition using a solvent to prepare the BCG-CWS compositions and preparing the CWS without the use of a solvent. Applicant urges that the Nomura II declaration shows that the including a solvent in the step of dispersing the BCG-CWS in the oil provides an emulsion having a more uniform particle size that lacks any large aggregates.

Applicant's arguments filed February 2, 2006 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is urging process limitations in a product claim. The claims are directed to an oil-in-water emulsion (a product) which comprises a Bacillus Calmette-Guerin cell wall skeleton encapsulated in an oil. It should be remembered that MPEP 2113 states:

> [E]ven though product-by-pro-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from the a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

Van Nest et al teach compositions (oil-in-water emulsions) comprising bacterial components, oils, emulsifying agents (dispersion-aiding solvent), detergents (surfactants) in the form of oil droplets. Van Nest et al teach that the composition of the invention comprise cell wall skeleton from *Mycobacteria*. Claim limitations such as

particle diameter of droplets would be inherent in the teachings of the prior art. Thus, the prior art anticipates the claimed invention.

To address Applicant's comments regarding the Declaration of Dr. Nomura, it appears the declaration is submitted to argue the difference in particle size of the BCG-CWS composition. The declaration compares using solvents and not using solvents to prepare the BCG-CWS composition. However, the declaration does not compare the oil-in-water of the prior art with the instantly claimed oil-in-water emulsion. There is no evidence provided to show that the claimed emulsion differs from that of the prior art since no comparison has been provided.

To address Applicant's comments regarding the Declaration of Dr. Kawabe which is submitted to show the differences between the morphologies of BCG-CWS suspended in a solvent (e.g. toluene) and the morphologies of BCG-CWS suspended in saline, it appears the data in this declaration is not relevant to the claimed invention which is directed to a oil-in-water emulsion and not a method of preparing an emulsion.

Although the use of a solvent such as ethanol or toluene is used in the process of making the claimed emulsion as evidenced by the Declaration II of Dr. Nomura, it should be noted that the prior art teaches that ethanol and acetone were both used in the preparation of the cell wall components of the oil-in-water emulsion (column 9).

There is nothing on the record to show that the oil-in-water emulsion of the prior art is not the same as the claimed oil-in-water emulsion.

8. The rejection under 35 U.S.C. 102(b) is maintained for claims 21, 23-25 and 26 for the reasons set forth on pages 4-6 paragraph 7 of the previous Office Action.

The rejection was on the grounds that Zbar et al teach compositions comprising BCG cell walls and mineral droplets (see the Abstract and pages 831-832). Zbar et al teach that the oil droplets of the prior art ranged from less than 1 μ to greater than 15 μ. Therefore, the claim limitation "the particle diameter of an oil droplet is 100 μm or less taught by the prior art. The claim limitation wherein the emulsion is negative for agglutination reaction with lectin" would be inherent in the teachings of the prior art. Claims limitations such as "(a) stirring a mixture of a Bacillus Calmette-Guerin cell wall skeleton, an oil, and an organic solvent to disperse the Bacillus Calmette-Guerin cell wall skeleton in the mixture; (b) evaporating off the organic solvent to form an oil wherein the Bacillus Calmette-Guerin cell wall skeleton is homogeneously dispersed, or an oil droplet wherein the Bacillus Calmette-Guerin cell wall skeleton is encapsulated in the oil; and then, (c) adding an aqueous solution containing a surfactant thereto, and emulsifying the mixture" are being viewed as process limitations. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Zbar et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that the claims are written in product-by-process terms. Applicant urges that the prior art does not teach or suggest that an organic solvent should be used during the preparation of an emulsion of the BCG-CWS. Applicant refers to the two Declarations filed under 37 CFR 1.132 of Dr. Nomura I and II and Dr. Kawabe. Applicant urges that the declarations are submitted to demonstrate the difference in particle size of the BCG-CWS composition using a solvent to prepare the BCG-CWS compositions and preparing the CWS without the use of a solvent. Applicant urges that the Nomura II declaration shows that the including a solvent in the step of dispersing the BCG-CWS in the oil provides an emulsion having a more uniform particle size that lacks any large aggregates.

Applicant's arguments filed February 2, 2006 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is urging process limitations in a product claim. The claims are directed to an oil-in-water emulsion (a product) which comprises a Bacillus Calmette-Guerin cell wall skeleton encapsulated in an oil. It should be remembered that MPEP 2113 states:

> [E]ven though product-by-pro-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from the a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

Zbar et al teach compositions comprising BCG cell walls and mineral droplets (see the Abstract and pages 831-832). Zbar et al teach that the oil droplets of the prior art ranged from less than 1 μ to greater than 15 μ. Claim limitations such as particle

diameter of droplets would be inherent in the teachings of the prior art. Thus, the prior art anticipates the claimed invention.

To address Applicant's comments regarding the Declaration of Dr. Nomura, it appears the declaration is submitted to argue the difference in particle size of the BCG-CWS composition. The declaration compares using solvents and not using solvents to prepare the BCG-CWS composition. However, the declaration does not compare the oil-in-water of the prior art with the instantly claimed oil-in-water emulsion. There is no evidence provided to show that the claimed emulsion differs from that of the prior art since no comparison has been provided.

To address Applicant's comments regarding the Declaration of Dr. Kawabe which is submitted to show the differences between the morphologies of BCG-CWS suspended in a solvent (e.g. toluene) and the morphologies of BCG-CWS suspended in saline, it appears the data in this declaration is not relevant to the claimed invention which is directed to a oil-in-water emulsion and not a method of preparing an emulsion.

Although the use of a solvent such as ethanol or toluene is used in the process of making the claimed emulsion as evidenced by the Declaration II of Dr. Nomura, it should be noted that the prior art teaches that ethanol and acetone were both used in the preparation of the cell wall components of the oil-in-water emulsion (column 9).

There is nothing on the record to show that the oil-in-water emulsion of the prior art is not the same as the claimed oil-in-water emulsion.

Status of Claims

9. No claims allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

11. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (571) 273-8300.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
April 3, 2006

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